

REMARKS

Applicants thank the Examiner for the interview held on Monday, July 19, 2010. In summary, Applicants discussed the cited Blumenfeld *et al.* reference distinguishing features from the presently claimed invention with the Examiner. No definitive conclusions were reached; however the discussion was appreciated. Claims 1, 8, and 9 are amended and claims 27 – 32 are newly added by the present communication. The subject amendments are supported by the specification, for example, in pages 10-12 (Summary of Invention), and the claims as originally filed. No new matter is introduced by the present amendments. Applicants submit that the amendments place the claims in condition for allowance. Accordingly, entry of the present amendments is respectfully requested.

Rejections under 35 U.S.C. § 112

Claims 1, 4-12, 15-16, 18-19, 21, and 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that there does not appear to be adequate written support for “indirectly linked with a phenotypic attribute” (instant claims 1 and 9) (page 3 of Office Action dated April 20, 2010). Applicants respectfully traverse the Examiner’s assertion.

Applicants respectfully assert that there is adequate support for the rejected language at least on pages 10, 13, 14 of the specification. Specifically, the bottom paragraph of page 13 states the following:

In accordance with the present invention, the preselection of the set of markers is based on genotype/phenotype associations with disease conditions or predispositions for disease conditions. [emphasis added].

Applicants would consider to replace the rejected language with the phrase “based on direct or indirect genotype/phenotype associations with disease conditions or predispositions for disease conditions” to expedite the prosecution of the claimed invention if necessary.

Rejections under 35 U.S.C. § 102

Claims 1, 4-12, 15-16, 18-19, 21, 24, and 25 remain rejected under 35 U.S.C. 102 (a) and (e) as being anticipated by Blumenfeld *et al.* (U.S. Patent No. 6,528,260). Applicants traverse the rejection for at least the reasons already of record and those that follow.

The present invention is directed to methods which interpret an individual's broad-based genetic profile, wherein the profile includes the individual's genomic genotype at a preselected set of markers, wherein the markers are preselected based on association or other studies to be directly or indirectly linked with a phenotypic attribute, and predicts the probability of that individual exhibiting particular phenotype(s) from one or more preselected markers. Currently amended claims 1 and 9 further recite the scoring matrix prioritizes markers with respect to one or more criteria selected from the group consisting of homology to another marker sequence of interest, synteny with respect to other marker sequences, ontological relevance, genomic relevance, quality of supporting research, and degree of phenotypic significance.

"[A]nticipation requires that the four corners of a single, prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). "Anticipation requires identity of invention. The claimed invention, as described in appropriately construed claims, must be the same as that of the reference in order to anticipate." *Glaverbel Societe Anonyme v. Northlake Marketing & Supply Inc.*, 45 F.3d 1550, 1554 (Fed. Cir. 1995).

Applicants respectfully submit that Blumenfeld *et al.* does not disclose each and every element of currently amended claims 1 and 9. Instead, Blumenfeld *et al.* provides disclosure of association studies linking a previously non-identified marker to a phenotypic attribute. The present invention is not based on identification of genetic markers per se.

A careful review of Blumenfeld *et al.* reveals that each paragraph cited by the Examiner merely describes conducting an association study, linking a known phenotype or trait with a marker which is not pre-selected for that particular phenotype. For example, col. 9, fourth

paragraph merely provides background on “genetic analysis of complex traits” (e.g., linkage analysis); col. 67, third paragraph provides “methods of genotyping an individual for biallelic markers”; col. 80, last two paragraphs provides a description of “population association studies”; and col. 84 first two paragraphs provides teaching regarding the selection of a population (*i.e.*, affected or trait positive) for examination in an association study. These passages describe association studies in order to identify genes or markers associated with known phenotypes. The markers cannot be pre-selected for the purpose of determining probability of exhibiting a particular attribute because the marker has not been identified previously, and there is no disclosure regarding a multivariate scoring matrix. In summary, Applicants respectfully assert that the Examiner interprets the disclosure of Blumenfeld *et al.* broader than it actually discloses.

Blumenfeld *et al.* shows that several approaches may be employed for certain studies, for example, a candidate gene approach (Blumenfeld *et al.* at col. 21, lines 14-17). This approach is based on the identification of genetic markers specifically derived from genes potentially involved in a biological pathway related to the trait of interest. Accordingly, candidate genes disclosed in Blumenfeld *et al.* include certain genes involved in drug metabolism (Blumenfeld *et al.* at col. 21, lines 21-26). Thus, Blumenfeld *et al.* reports the “discovery of a set of novel DME-related biallelic markers” (Blumenfeld *et al.* at col. 10, lines 34-35). For example, Blumenfeld *et al.* reports an association between asthma and the biallelic markers of the MGST-II gene (Example 3), and a further association between the side effects of treatment with the anti-asthmatic drug Zyflo and the identified biallelic markers (Example 4). Thus, the focus of the teachings of Blumenfeld *et al.* is the elucidation of a gene or marker responsible for a known phenotype. The claimed invention does not require or envision identification of new markers (*i.e.*, the markers are known and pre-selected for the probability study).

Further, Blumenfeld *et al.* does not disclose a method of reporting information obtained from an interpretation of an individual’s broad-based genetic profile to that individual, in which the phenotypic attributes are subjected selection criteria (*i.e.*, “applying one or more selection criteria for each of the one or more phenotypic attributes”), comparing a multivariate scoring matrix to the marker set to obtain a single risk score for each selected phenotype (*i.e.*,

“determining the probability of exhibiting a phenotypic attribute based on the marker score”), and combining with other information (*e.g.*, “information that is relevant to the individual’s probability of exhibiting a phenotypic characteristic”), and communicating the results to the individual, for example, in a report (as in claim 9). Thus, the disclosure of Blumenfeld *et al.* is in fact much narrower than asserted by the Examiner.

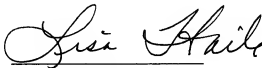
Based on the reasons set forth above, Applicants respectfully submit that the currently amended claims clearly distinguish over Blumenfeld *et al.* Accordingly, reconsideration and withdrawal of the anticipation rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the claims are in condition for allowance, and a notice to that effect is respectfully requested.

The Commissioner is hereby authorized to charge the total amount of \$221.00 to Deposit Account No. 07-1896 to cover the One-Month Extension of Time fee (\$65.00) and the extra claims fees (\$156.00) for six (6) additional dependent claims pending in the present application. Additionally, the Commissioner is authorized to charge any other fees associated with the filing submitted herewith, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. The Examiner is invited to contact Applicant's undersigned representative if there are any questions relating to this application.

Respectfully submitted,



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